Remarks

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

The Office Action is non-final. Claims 1-16 are currently pending. Claims 13-16 have been withdrawn from further consideration as being directed to a non-elected invention. Claims 1 and 16 have been amended to further clarify and define the invention. Support for claim 1 is based on page 15, line 23, to page 16, line 11 of the present specification.

Entry of the present Amendment is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kitamura *et al.*, U.S. Patent No. 5,676,966 (hereinafter "Kitamura"), in view of Bischoff *et al.*, U.S. Patent No. 4,770,876 (hereinafter "Bischoff").

Applicants respectfully traverse the rejection.

The Examiner's Position:

The Examiner asserts that the present application is obvious in light of the above cited references, as indicated on pages 3-4 of the outstanding Office Action.

Based on the following, Applicants contend that the Examiner's position is not supportable, thereby making the presently claimed invention unobvious over the cited references.

Applicants' Position

The presently claimed invention is directed to a feed additive composition for ruminants which has a biologically active substance coated with a coating composition. The coating composition comprises at least one protective material selected from the group consisting of a hardened animal fat, a hardened vegetable oil, a linear or branched, saturated or unsaturated aliphatic monocarboxylic acid having 12 to 22 carbon atoms, a fatty acid ester, and a wax group;

lecithin; and at least one preservative selected from a propionic acid or a salt thereof, a sorbic acid or a salt thereof, a benzoic acid or a salt thereof, a dehydroacetic acid or a salt thereof, parahydroxybenzoic acid esters, an imazalil, a thiabendazole, an orthophenyl phenol, an orthophenyl phenol natrium, and a diphenyl. Further, the preservative is dispersed in the vicinity of the surface of the feed additive composition.

As indicated in MPEP § 2143, the Examiner must resolve the factors described in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which provides the controlling framework for an obviousness analysis, before utilizing the rationales that were established in *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Differences between the Invention and the Cited References

Applicants provide the following information regarding the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue.

Applicants have amended claim 1 to distinguish the presently claimed invention from the above cited references.

Amended claim 1 defines the preservative as being dispersed in the vicinity of the surface of the feed additive composition, not at the core. Applicants submit that amended claim 1 emphasizes that the position of the preservative is limited, *i.e.*, the preservative is contained in the feed additive not uniformly, but partially. Particularly, the preservative is spread in the coating composition which is arranged outside the biologically active substance.

This specific structure of the present invention achieves the following effect:

> *[0044] A preservative agent serves to inhibit a growth of mold, bacteria, etc. or exhibits an antibacterial action, and an antifungal agent etc. can be employed for such purposes. When contained in a rumen bypass product, the preservative is believed to minimize attack and breakdown of a biologically active substance by rumen microorganisms as well as intrusion in the vicinity of the surface of the rumen bypass product, resultantly working to prevent a disintegration. Particularly, when the preservative is blended and dispersed in a coating composition which coats the biologically active substance, such preservative can*

> *efficiently perform its preservative function without damaging the biologically active substance. As for an amount of the preservative to be added, an excessive addition is likely to affect microbial propagation and growth, while an insufficient addition may defeat an expected effect. Thus, the content of preservative should desirably be 0.01 to 2.0% by weight, preferably 0.1 to 1.0% by weight, based on a total amount of the rumen bypass product. The preservative is preferably in the form of a fine powder. Also, it is desirable that the preservative be pulverized for use, as may be needed. It is also possible to improve a rumen bypass ratio by 10 to 50% when the preservative is dispersed in the coating composition so that attack by the rumen microorganisms may be inhibited (See paragraph [0044], pages 15-16, of the present specification; Emphasis added).*

On page 4 of the Office Action, the Examiner asserts that "it would have been obvious to the skilled artisan to include a preservative to in the coating **and** the core which is known to be compatible not only for the intended use of the composition, but also compatible with the components present in the composition (emphasis added)." Applicants respectfully disagree.

Regarding the Kitamura reference, the Examiner acknowledges on page 3 (last line) of the Office Action that "Kitamura does not teach the addition of propionic acid." Inherently, Applicants submit that Kitamura does not disclose or imply a preservative at all.

Concerning the Bischoff reference, while the Examiner suggests on page 4 (first paragraph) of the Office Action that "Bischoff et al teaches the use of propionic acid as a preservative for livestock compositions (col 8 lines 53-56) where other suitable components include lecithin (col 8 lines 51-52) and amino acids (col 4 lines 6-11)," Applicants submit that Bischoff explains, at column 8, lines 20-57:

> *"[T]he active compound is administered to the livestock by conventional method....The active compound may be present **in the formulations** alone or **mixed** with other production-promoting active compounds such as antibiotics, mineral feedstuffs, trace element compounds, vitamins, non-protein compounds, colorants, antioxidants, aromas, emulsifiers, flow auxiliaries, preservatives and tabletting auxiliaries....Emulsifiers are, for example, esters of lactic acid, and lecithin....Preservatives are, for example, citric acid and propionic acid...."(Emphasis added).*

Specifically, the Bischoff reference merely discloses that preservatives may be compounded with the active compound, which is made into the formulation for livestock animals. Thus, the preservatives are just one of the admixtures for the mixed formulation.

Accordingly, Bischoff does not disclose or teach the preservatives wrapping the active compound itself, which fits the Examination's view (see page 4, second paragraph, of the Office Action), *i.e.*, "[B]ischoff et al does not teach the addition of the preservative in the coating."

Likewise, Applicants submit that lecithin is regarded as an emulsifier which may be only mixed with the active compound for the formulation. Applicants note that Bischoff does not disclose lecithin for coating the active compound itself.

Applicants also submit that the Bischoff reference basically does not conceive of the idea of a coating composition for covering the active compound, which enables the substance to be stably protected within the first stomach compartment (*i.e.*, the rumen) of ruminants and to be released in the abomasum and/or the subsequent digestive tract.

Since the Bischoff reference merely recites additives which are possibly mixed together with the active compound, such as preservatives, emulsifiers, *etc.*, Applicants submit that one of ordinary skill in the art would, as a practical matter, look upon the preservatives in the Bischoff references for preventing the formulation from going bad.

In view of the above, if the preservatives of Bischoff were to be combined with the feed additive composition of Kitamura, which does not disclose preservatives, Applicants submit that one of ordinary skill in the art would not be motivated to combine the references so as to integrate the feed additive composition with the preservatives directly or to limit the position of the preservatives uniquely.

Applicants also submit that the unlikely combination would lead the feed additive composition to include a preservative in both the coating **and** the core, as the Examiner points out.

Consequently, the combination never attains the specific structure such as in the presently claimed invention, *i.e.*, the preservative is dispersed in the vicinity of the feed additive compound surface.

Applicants submit that based on the differences discussed above, the Examiner has not resolved the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue, and therefore the rationale the Examiner provides for the rejection is improper.

Applicants submit that the differences between the prior art references and the presently claimed invention are clear. Applicants note that although the above comments discuss the Kitamura and Bischoff references individually, this was only for discussing these references in terms of the *Graham* factor analysis. Applicants submit that taking the above *Graham* analysis in mind, the combination of Kitamura and Bischoff does not lead to the presently claimed invention.

In light of the above amended claims and remarks, Applicants submit that the assertions made by the Examiner regarding the Kitamura and Bischoff references are incorrect, thus failing to support the Examiner's position. Accordingly, based on the differences between the presently claimed invention and the above references, the Kitamura and Bischoff references do not teach or suggest the presently claimed invention.

The secondary reference, Bischoff, fails to remedy the deficiencies of the Kitamura reference.

Since amended claim 1 is not obvious to one of ordinary skill in the art, claims 2-12, which ultimately depend from claim 1, are unobvious over the Kitamura and Bischoff references for the same reasoning discussed above.

Additionally, Applicants note that the counterpart Canadian patent has been issued as No. 2,556,781.

Also, the counterpart Japanese patent has been issued as No. 3,728,738 (filed as JP2004-335286) after a preliminary amendment added claim 2 to claim 1. Claim 2, where a content of the preservative is defined in the specified range is judged as category "A" in the International Search Report.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Conclusion

Applicants respectfully submit that the rejection raised by the Examiner has been overcome, and that the present application now stands in condition for allowance.

Should there be any outstanding matters that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla at the telephone number below, in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 23-0975 for any additional fees required under 37 C.F.R. §§1.16 or 1.17.

Respectfully submitted,

Akira OKUTANI et al.

By /Paul D. Pyla/ Digitally signed by /Paul D. Pyla/ DN: cn=/Paul D. Pyla/, o, ou, email=ppyla@wenderoth.com, c=US Date: 2010.09.10 08:48:34 -04'00'

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